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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,275	08/01/2005	Wei-Ping Min	4767-217 LAB	9949

24223 7590 09/17/2010

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EXAMINER	
CHONG, KIMBERLY	
ART UNIT	PAPER NUMBER
1635	
MAIL DATE	DELIVERY MODE
09/17/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,275	MIN ET AL.	
	Examiner	Art Unit	
	KIMBERLY CHONG	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) *1-21,23,25,26,32-46,50 and 54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22,24,27-31,47-49,51-53 and 55-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 07/21/2010 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 01/21/2010 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 07/21/2010, claims 1-61 are pending in the application. Claims 22, 24, 27-31, 47-49, 51-53 and 55-61 are currently under examination. Claims 1-21, 23, 25-26, 32-46, 50 and 54 are withdrawn as being drawn to a non-elected invention

Response to Arguments

Claim Rejections - 35 USC § 103

The rejection of claims 22, 24, 27-31, 47-49, 51-53 and 55-61 under 35 U.S.C. 103(a) as being unpatentable over Qian et al. (US 2004/0043483 of record), Li et al. (Journal of Immunology 2001, Vol. 166: pages 5619-5628 of record) and Tuschl et al. (WO 02/44321 cited on PTO 892 mailed 05/21/2007) is maintained for the reasons of record.

Applicant's arguments filed 07/21/2010 have been fully considered but they are not persuasive. Applicant argues Qian et al. is not relevant to the presently claimed

invention because the reference is directed to the use of antisense technology which is not the same as siRNA technology. Applicant argues the mechanisms of action of an antisense molecule, which blocks mRNA translations, is not the same as siRNA which works by degrading the mRNA and states that siRNA technology is much more efficient and effective than antisense technology.

Applicant argues Li et al. is also not relevant because it is directed to the use of an antibody which is a different technology to that of siRNA and argues Tuschl et al., while teaching RNA interference technology in general, does not teach or suggest targeting the presently claimed endogenous genes.

In response, it was known in the art at the time of filing of the instant invention that IL-12 production from antigen presenting cells such as dendritic cells plays a key role in regulation of autoimmune responses and as shown by Li et al., neutralization of the production of IL-12 using antibodies reduced acute liver graft rejections. Further Li et al. teach decreasing the activity of IL-12 produced from dendritic cells promotes T cell apoptosis, which would be considered suppressing T cell activity that is responsible for rejection of organs and tissue. Thus Li et al. provide one of ordinary skill in the art with the motivation to reduce IL-12 production in efforts to regulate autoimmune responses.

It was also well known that reducing the expression of endogenous genes such as IL-12 using antisense compounds was a method for preventing or minimizing transplant rejections or autoimmune diseases as taught by Qian et al. (of record).

At the time of filing of the instant invention, RNA interference was emerging as a new technology to reduce any desired target gene because the use of siRNA to inhibit

gene expression is effectively more sequence specific than using other inhibitory compounds such as antisense molecules and RNAi using dsRNA is a more potent method as taught by Tuschl et al. One of ordinary skill in the art would have predictably followed the teachings of Tuschl et al. to make the siRNA to possess specific homology to the entire exon region of a gene encoding IL-12 as this is merely a predictable use of prior art elements according to their established functions. It would have been a matter of routine experimentation to design such a molecule in order to efficiently target the expression of IL-12.

There is an implicit motivation to combine the teachings of Tuschl et al. with that of Qian et al. to generate a more efficient method of reducing IL-12 expression because the use of siRNA is a known alternative to silencing gene expression as compared to antisense technology and provides a specific advantage of improved efficiency.

Moreover, one would have a reasonable expectation of success given that Tuschl et al. teach how to make and use virtually any siRNA to any gene provided the target sequence is known and teach that methods of RNA synthesis are known in the art, as evidenced by the examples provided therein and one would have expected to be able use a dendritic cell comprising an siRNA in the methods of treatment of an immune disorder as shown by Qian et al. and Li et al.

Thus in the absence of evidence to the contrary, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Thursday between 6 and 3 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact Christopher Low at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image

problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/
Primary Examiner
Art Unit 1635